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10/599,504	11/03/2006	Jonas Lundahl	05432/1201132-US1	9987

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DARBY & DARBY P.C.
P.O. BOX 770
Church Street Station
New York, NY 10008-0770

EXAMINER	
PHILLIPS, WELDON PATRICK	
ART UNIT	**PAPER NUMBER**
4121	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/599,504	LUNDAHL ET AL.	
	Examiner	Art Unit	
	WELDON PHILLIPS JR.	4121	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *23-51* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *23-51* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *11/28/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This application for patent entered the national stage in the United States of America under 35 USC 371 from PCT/DK05/000222, filed March 31, 2005, claiming the benefit of both (1) Danish Patent Application No. PA 2004 00540, filed April 2, 2004 and (2) U.S. Provisional Application No. 60/559,096, filed April 2, 2004.

Claims 23-28 and 30-51 receive the benefit of U.S. Provisional filing date of April 2, 2004.

Claim Status

Claims 23 and 24, as amended by Preliminary Amendment filed November 3, 2008, and claims 25-51 are now pending.

Acknowledgement

Receipt of copies of the International Search Report and the International Preliminary Report on Patentability, reflecting the International Searching Authority's non-binding opinion regarding novelty, inventive step and industrial applicability, is acknowledged and the contents of said reports have been considered by the examiner.

Information Disclosure Statement

An Information Disclosure Statement (IDS) was timely filed by applicant on November 28, 2006 in compliance with 37 CFR § 1.97(b). However, the IDS fails to comply with the provisions of 37 CFR § 1.97, 37 CFR § 1.98 and/or MPEP § 609 for the following reasons.

The IDS filed November 28, 2006 fails to comply with the requirements of 37 CFR § 1.98(a)(2), which requires applicants to provide a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. Applicants provided no copy of foreign patent reference BC for the application file. The examiner has obtained a copy of the reference BC by other means, placed a copy of BC in the application file and properly considered the reference. Therefore, applicant needs to take no action as to foreign patent reference BC.

The IDS filed November 28, 2006 fails to comply with the requirements of 37 CFR § 1.97, 37 CFR § 1.98 and MPEP § 609, because it includes a citation to an international search report. International search reports should not be cited on the IDS. It is sufficient that the references contained on said search report were separately listed on the IDS and that copies of any international search reports are provided. Therefore, a separate citation for the international search report itself is inappropriate, the international search report has been stricken from the IDS and no further action is necessary on the part of the applicant.

Specification

The specification has not been proofed to the extent necessary to uncover the presence of all minor errors. At this time, applicant's cooperation is requested in correcting any and all errors of which applicant is or may become aware of in the specification.

Claim Objection - Duplicate Claims

Applicant is advised that should claim 23 be found allowable, claim 24 will be objected to under 37 CFR § 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k). In the instant application, applicant claims "[a] method for treating impaired respiratory function in a human patient suffering from sleep apnea" in claim 23 and "[a] method for treating sleep apnea in a human patient" in claim 24.

Sleep apnea may be defined as "a temporary interruption of breathing that happens repeatedly during sleep" (Merck Manual on Health & Aging, http://www.merck.com/pubs/mmanual_ha/sec3/ch31/ch31e.html). Applicants indicate that "treatment of impaired respiratory function is to mean improving or alleviating the respiratory function in patients suffering from sleep apnea, over a period of sleep, from 10 minutes to 10 hours" (pg. 6 of the Specification). Nothing in the disclosure differentiates "treating sleep apnea in a human patient" from "treating impaired respiratory function in a human patient suffering from sleep apnea," and examiner can find no logical reason to do so. In other words, the treatment of the underlying impairment in respiratory function in sleep apnea patients in claim 23 is one and the same as the treatment sleep apnea in claim 24. Absent evidence to the contrary,

applicant is advised that if claim 23 should be found allowable, claim 24 will be objected to under 37 CFR § 1.75 as being a substantial duplicate thereof.

Claim Rejections – 35 USC 112 2nd Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 40-42 are rejected under 35 USC 112 second paragraph, as being indefinite for failing to point out and distinctly claim the subject matter which applicant regards as his invention.

The expressions "intermediate term treatment," "short term treatment" and "long term treatment" do not set forth the metes and bounds of the claims. Recourse in the specification is insufficient.

Claim Rejections – 35 USC 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 23-28 and 39-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Radulovacki (WO 00/51590, cited by applicant on IDS), in view of Lancel (U.S. Patent 5,929,065).

Applicant claims methods of treating impaired respiratory function in human patients suffering from sleep apnea (23) and sleep apnea in a human patient (24), comprising administering effective amounts of gaboxadol per day, wherein the type of sleep apnea is either central (25), obstructive (26) or mixed (27).

Radulovacki teaches the administration of agents, among them THIP, to patients in amounts effective to treat sleep-related breathing disorders, among them central, obstructive and mixed apneas. The relevant teachings of Radulovacki include disclosures of two genuses, (1) agents having agonistic activity at presynaptic inhibitory receptors for glutamatergic/glycinergic terminals within the central nervous system for the prevention or amelioration of sleep-related breathing disorders, more generally GABA receptor agonists and (2) sleep-relating breathing disorders. In both cases, the relevant species to the instant application, THIP and all three types of sleep apnea, central, obstructive and mixed, are specifically taught. Importantly, THIP is an acronym for the chemical compound 4,5,6,7-tetrahydroisoxazole[5,4-*c*]pyridin-3(*2H*)-one or 4,5,6,7-tetrahydroisoxazole[5,4-*c*]pyridin-3-ol, CAS Reg. # 64603-91-4, hereinafter known as gaboxadol (Merck Index, https://themerckindex.cambridgesoft.com/TheMerckIndex/default.asp?formgroup=basenp_form_group&dataaction=db&dbname=TheMerckIndex).

Radulovacki fails to specifically recite that these agents could be administered on a daily basis, disclosing rather that specific doses may be calculated according to such factors as body weight or body surface and that refinement of the calculations necessary to determine the appropriate dosage for treatment of sleep-related breathing disorders is routinely made by those of ordinary skill in the art without undue experimentation and that appropriate dosages may be ascertained through use of established assays for determining dosages (pg. 17). These principles extend to schedules of administration, e.g. on a daily basis.

Because sleep is something all human beings generally need to have every day, it would be obvious to a person of ordinary skill in the art to also determine dosing schedules that optimally treats sleep apnea and the associated impairment in respiratory function on a daily basis. To further support examiner's position, Lancel teaches daily administration of gaboxadol to treat sleep disorders (column 3, line 56 and claim 5). Absent evidence to the contrary, it would have been obvious to a person having ordinary skill in the art to combine the teachings of Radulovacki and Lancel to produce the claimed invention of claims 23-27.

Applicant claims the method of claim 23, wherein the gaboxadol increases slow wave sleep in the patient, thereby improving respiratory function (28). Radulovacki fails to specifically recite that these agents may be used to increase slow wave sleep in the patient, thereby improving respiratory function. Slow wave sleep, also known as NREM sleep and non-REM sleep, is a state of deep usually dreamless sleep, with intervening periods of REM sleep, also characterized by delta waves and low levels of autonomic

physiological activity (Merriam-Webster Medical Dictionary, http://medical.merriam-webster.com/medical/medical?book=Medical&va=slow-wave+sleep). Increases in slow wave sleep would be an expected property of treatment with an effective amount of gaboxadol, due to improved respiration, less frequent apnea events and fewer interruptions in sleep. In the alternative, Lancel teaches that gaboxadol dose-dependently increases non-REM sleep, lengthens the duration of non-REM episodes without decreasing REM sleep episodes and enhances EEG-delta activity during non-REM sleep (column 3, line 60). Absent evidence to the contrary, it would have been obvious to a person having ordinary skill in the art to combine the teachings of Radulovacki and Lancel to produce the claimed invention of claims 28.

Applicant claims the method of claim 23, wherein the human patient is selected from elderly or adult patients (39). Radulovacki fails to specifically recite that these agents may be useful in elderly or adult patients, although he does note that obstructive sleep apnea is present in significant numbers of working age men and women, with peak prevalence of this condition in the sixth decade (pg. 2). Radulovacki further discloses that the specific doses may be calculated according to such factors as body weight or body surface and that refinement of the calculations necessary to determine the appropriate dosage for treatment of sleep-related breathing disorders is routinely made by those of ordinary skill in the art without undue experimentation and appropriate dosages may be ascertained through use of established assays for determining dosages (pg. 17). These principles extend to the age of patient populations. Because sleep is something all human beings generally need to have every day, it would be

obvious to a person of ordinary skill in the art to also ascertain the relevance and effect of factors like age so that physicians may optimally treat sleep apnea and the associated impairment in respiratory function in patients of all ages. To further support examiner's position, Lancel teaches that gaboxadol is particularly suitable for the treatment of elderly patients (column 3, line 20). Absent evidence to the contrary, it would have been obvious to combine the teachings of Radulovacki and Lancel to produce the claimed invention of claim 39.

Applicant claims the method of claim 23, wherein the duration of treatment is intermediate (40) short (41) or long term (42), where the aforementioned terms are defined as 1-4 weeks, less than 1 week and greater than 4 weeks, respectively. Radulovacki fails to specifically recite that treatment could be intermediate, short or long term, disclosing that the specific doses may be calculated according to such factors as body weight or body surface and that refinement of the calculations necessary to determine the appropriate dosage for treatment of sleep-related breathing disorders is routinely made by those of ordinary skill in the art without undue experimentation and appropriate dosages may be ascertained through use of established assays for determining dosages (pg. 17). These principles extend to treatment cycles and duration of therapy. Because sleep is something all human beings generally need to have every day, it would be obvious to a person of ordinary skill in the art to also determine a treatment cycle or duration of therapy that optimally treats sleep apnea and the associated impairment in respiratory function. To further support examiner's position, Lancel teaches daily administration of gaboxadol to treat sleep disorders (column 3, line

56 and claim 5), without suggesting limitations on treatment duration. If limitations become apparent, one of ordinary skill in the art will be able to make those in the normal course of therapy. Absent evidence to the contrary, it would have been obvious to combine the teachings of Radulovacki and Lancel to produce the claimed invention of claims 40-42.

Claim 29 is rejected under 35 U.S.C. 103(a) as being unpatentable over Radulovacki in view of Lancel as applied to claims 23-28 above, and further in view of Vandeputte and Sanchez.

Applicant claims the method of claim 29, wherein the human patient suffers from sleep apnea and depression at the same time. Radulovacki and Lancel fail to specifically recite that these agents may be used in the treatment of patients suffering from both sleep apnea and depression. Although the link between sleep apnea and depression is complicated at best, Vandeputte teaches that high percentages of people who present with sleep apnea describe themselves as depressed, report symptoms consistent with major depressive episodes and score similarly to other sleep disorder sufferers on the BDI scale consistent with other sleep disorders (pg. 343-345, Tables 1-3). Sanchez teaches that effective CPAP therapy leads to a statistically significant improvement in depression levels measured on the BDI scale (Sanchez, pg. 644-645). In spite of the complex etiology of depression, it follows that other therapies that effectively treat sleep apnea patients will be of benefit to those who happen to also suffer from some form of depression. Absent evidence to the contrary, it would have been obvious to a person having skill in the art to combine the teachings of

Radulovacki, Lancel, Vandeputte and Sanchez to produce the claimed invention of claim 29.

Claims 30-32 and 43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Radulovacki in view of Lancel as applied to claims 23-28 above, and further in view of the Krogsgaard-Larsen patent and Ebert.

Applicant claims the method of claim 23, wherein the gaboxadol is: in the form of an acid addition salt (claim 30), including its hydrochloric or hydrobromic salts (31), in its zwitterion hydrate, anhydrate (30) or monohydrate form (32) or its crystalline form (43). Radulovacki fails to specifically recite that gaboxadol may be in its acid salts, zwitterion or crystalline forms. Much of this was taught in a variety of references 20 to 30 years ago. In other words, absent special teachings in the specification about particular gaboxadol salts, gaboxadol zwitterion's hydration level and/or the crystalline forms of gaboxadol, these are all obvious variants of gaboxadol. Lancel further teaches that gaboxadol may be formulated and administered in the form of its pharmaceutically acceptable acid addition salts for purposes of stability, convenience of crystallization, increased solubility and the like (column 3, line 49). Krogsgaard-Larsen teaches the acid addition salt forms of gaboxadol, including the hydrochloric and hydrobromic salt forms and the preparation thereof, as well as gaboxadol's zwitterion form and the preparation of crystalline gaboxadol in its zwitterion form (pg. 4, 6 and 8, reaction schemes I & II, and Examples 1 and 3). Ebert teaches utilizing the zwitterion base of gaboxadol, a pharmaceutically acceptable acid addition salt thereof and anhydrate or hydrate salts of gaboxadol (pg. 6). Absent evidence to the contrary, it would have been

obvious to a person having skill in the art to combine the teachings of Radulovacki, Lancel, the Krogsgaard-Larsen patent and Ebert to produce the claimed invention of claims 30-32 and 43.

Claims 33-38 and 44-48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Radulovacki in view of Lancel as applied to claims 23-28 above, and further in view of the Krogsgaard-Larsen patent.

Applicant claims the method of claim 23, wherein gaboxadol is administered orally (claim 33), wherein gaboxadol is administered as an oral dosage form (34), wherein the oral dosage form is a solid dosage form (35), wherein the oral dosage form is a tablet or capsule (36), wherein the oral dosage form is a liquid oral dosage form (37) and wherein the oral dosage form comprises from 2.5 mg to 20 mg of gaboxadol (38). Radulovacki teaches that administration of agents may be by any systemic means including oral administration (pg. 7). With respect to dosing, Radulovacki teaches that individuals diagnosed with sleep-related breathing disorders are administered agents or composition thereof in an amount effective to prevent or suppress such disorders. According to Radulovacki, the specific dose may be calculated according to such factors as body weight or body surface and that refinement of the calculations necessary to determine the appropriate dosage for treatment of sleep-related breathing disorders is routinely made by those of ordinary skill in the art without undue experimentation and appropriate dosages may be ascertained through use of established assays for determining dosages (p. 17). Lancel teaches that $GABA_A$ agonists can be formulated in a manner well-known in the art using common

pharmaceutical adjuvants and optionally in combination with other active substances to form common galenic preparations, such as tablets, coated tablets, capsules, powders, suspensions, injectable solutions or suppositories (column 3, line 25). In a preferred embodiment and claim 5, Lancel teaches that non-allosteric $GABA_A$ agonists are administered in a dose of 5 to 50 mg per day (column 3, line 54 and claim 5). Krogsgaard-Larsen teaches that gaboxadol may be formulated with the usual carriers for tablets, pellets, capsules, suppositories, solutions, emulsions, aqueous suspensions and other suitable administration forms (pg. 9) and that a preferred tablet or capsule formulation for oral administration to produce a desired therapeutic effect at GABA receptors contains 0.1 to 200 mg, preferably 1 to 100 mg, especially 5 to 50 mg (pg. 9-10). The range cited by Lancel and the most preferred range cited by Krogsgaard-Larsen overlaps 86% of applicants claimed range. Absent evidence to the contrary, it would have been obvious to combine the teachings of Radulovacki, Lancel and the Krogsgaard-Larsen patent to produce the claimed invention of claims 33-38.

Applicant claims the method of claim 34, wherein an oral dosage form comprises an amount from 2.5 to 20 mg of gaboxadol (44) or 5 to 15 mg gaboxadol (45), said amount being effective during a substantial amount of a single sleep period, wherein said substantial portion is 50% or more (46) or 80% or more (47), or wherein said single sleep period is from one to eight hours (48). Radulovacki teaches that administration of agents may be by any systemic means including oral administration (pg. 7). Radulovacki teaches that specific doses may be calculated according to such factors as body weight or body surface and that refinement of the calculations necessary to

determine the appropriate dosage for treatment of sleep-related breathing disorders is routinely made by those of ordinary skill in the art without undue experimentation and appropriate dosages may be ascertained through use of established assays for determining dosages (p. 17). These principles are again relevant here. Because sleep is something all human beings generally need to have every day, it would be obvious to a person of ordinary skill in the art to also determine a treatment regimen that optimally treats sleep apnea and the associated impairment in respiratory function over a substantial portion of a sleep period, be that 1 hour, 8 hours or somewhere in between. Lancel teaches that $GABA_A$ agonists can be formulated in a manner well-known in the art using common pharmaceutical adjuvants and optionally in combination with other active substances to form common galenic preparations, such as tablets, coated tablets, capsules, powders, suspensions, injectable solutions or suppositories (column 3, line 25). In a preferred embodiment and claim 5, Lancel teaches that non-allosteric $GABA_A$ agonists are administered in a dose of 5 to 50 mg per day (column 3, line 54 and claim 5). Krogsgaard-Larsen teaches that gaboxadol may be formulated with the usual carriers for tablets, pellets, capsules, suppositories, solutions, emulsions, aqueous suspensions and other suitable administration forms (pg. 9) and that a preferred tablet or capsule formulation for oral administration to produce a desired therapeutic effect at GABA receptors contains 0.1 to 200 mg, preferably 1 to 100 mg, especially 5 to 50 mg (pg. 9-10). Note that the range cited by Lancel and the most preferred range cited by Krogsgaard-Larsen overlaps 86% and 100% of applicants claimed ranges, respectively. Absent evidence to the contrary, it would have been

obvious to combine the teachings of Radulovacki, Lancel and the Krogsgaard-Larsen patent to produce the claimed invention of claims 44-48.

Claims 49-51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Radulovacki in view of Lancel and the Krogsgaard-Larsen patent as applied to claims 33-38 and 44-48 above, and further in view of the Krogsgaard-Larsen NPL reference and Elema.

Applicant claims the method of claim 44, wherein the amount of gaboxadol is released from a composition for controlled release (49), wherein 50% to 100% of the amount of the amount is released within a period of three hours from administration (50) or 80% to 100% of the amount is released within a period of five hours from administration (51). Radulovacki teaches that specific doses may be calculated according to such factors as body weight or body surface and that refinement of the calculations necessary to determine the appropriate dosage for treatment of sleep-related breathing disorders is routinely made by those of ordinary skill in the art without undue experimentation and appropriate dosages may be ascertained through use of established assays for determining dosages (p. 17). Radulovacki also teaches that time-released pellets or other depot forms of administration may be used (p.17). The Krogsgaard-Larsen NPL reference teaches the relatively short half-life of gaboxadol of less than 2 hours in man after oral administration of a clinically relevant dose, and suggests the importance of developing sustained release preparations (pg. 838). Compositions providing for modified release profiles are nothing new. They can be optimized to provide desired release profiles in light of relevant factors including dosing

limitations, bioavailability, solubility, stability, elimination half-life, therapeutic window, first-pass metabolism and the pharmacokinetic-pharmacodynamic relationship. To that end, Elema teaches solid modified release dosage forms of gaboxadol, wherein approximately 75% of the gaboxadol is released by 3 hours and over 90% is released by 5 hours utilizing a commonly used in vitro USP dissolution method (pg. 11, Figure 3 and claims 1-12 in light of claim 15). Absent evidence to the contrary, it would have been obvious to combine the teachings of Radulovacki, Lancel, the Krogsgaard-Larsen patent, the Krogsgaard-Larsen NPL reference and Elema to produce the claimed invention of claims 49-51.

Claim Disposition

Claims 23-51, as amended, are rejected at this time. No claims are allowed.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to WELDON PHILLIPS JR. whose telephone number is (571)-270-7673. The examiner can normally be reached Monday through Thursday & every other Friday between 7:30 AM and 5:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Patrick Nolan can be reached on 571-272-0847. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/WP/
Examiner, Art Unit 4121

/Patrick J. Nolan/
Supervisory Patent Examiner, Art Unit 4121